

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-13 (Withdrawn).

14 (Currently amended). A composition, comprising:

a cerumenolytically acceptable enzyme in an amount effective to assist in the removal of human cerumen from the external ear canal; and

an aqueous otologically acceptable vehicle, said vehicle including a bicarbonate in an amount effective to assist in the removal of human cerumen from the external ear canal.

15 (Original). The composition of claim 14 wherein said cerumenolytically acceptable enzyme is selected from the group consisting of lipases, proteases, amylases, and combinations or mixtures thereof.

16 (Original). The composition of claim 15 wherein said cerumenolytically acceptable enzyme is a proteolytic enzyme.

17 (Original). The composition of claim 16 wherein said proteolytic enzyme is selected from the group consisting of pancreatin, trypsin, subtilisin, collagenase, keratinase, carboxypeptidase, papain, bromelain, aminopeptidase, elastase, Aspergillo peptidase, pronase E (from *S. griseus*), dispase (from *Bacillus polymyxa*), and combinations or mixtures thereof.

18 (Original). The composition of claim 16 wherein said proteolytic enzyme comprises a microbially derived enzyme.

19 (Original). The composition of claim 16 wherein said proteolytic enzyme comprises an alkyl trypsin.

20 (Original). The composition of claim 19 wherein said alkyl trypsin comprises methyl trypsin.

21 (Original). The composition of claim 14 wherein said vehicle comprises a demulcent.

22 (Original). The composition of claim 14 wherein said vehicle comprises a surfactant.

23 (Original). The composition of claim 14 wherein said vehicle comprises a

perservative.

24 (Original). The composition of claim 14 wherein said vehicle comprises a buffer.

25 (Original). The composition of claim 21 wherein said demulcent is selected from the group consisting of povidone, polyvinyl alcohol, glycerin, propylene glycol, polyethylene glycol, and cellulose derivatives.

26 (Original). The composition of claim 22 wherein said surfactant is selected from the group consisting of polysorbates, 4-(1, 1, 3, 3-tetramethylbutyl) phenol/poly(oxyethylene) polymers, poly(oxyethylene)-poly(oxypropylene) block copolymers, polyethylene glycol esters of fatty acids, and polyoxypropylene ethers of higher alkanes (C₁₂ -C₁₈).

27 (Original). The composition of claim 23 wherein said preservative is selected from the group consisting of poly[dimethylimino-2-butene-1,4-diyl]chloride-alpha-[4-tris(2-hydroxyethyl)ammonium]dichloride, benzalkonium halides, alexidine salts, chlorhexidine salts, hexamethylene biguanimides and their polymers; and combinations or mixtures thereof.

28 (Original). The composition of claim 24 wherein said buffer is selected from the group consisting of citrate, phosphate, borate, acetate, Tris, salts of any of the foregoing, and combinations or mixtures thereof.

29 (Original). The composition of claim 25 wherein said demulcent is glycerin.

30 (Original). The composition of claim 26 wherein said surfactant is a poly(oxyethylene)-poly(oxypropylene) block copolymer.

31 (Original). The composition of claim 27 wherein said preservative is a benzalkonium halide.

32 (Original). The composition of claim 28 wherein said buffer is a citrate or salt thereof.

33 (Original). The composition of claim 14 wherein said cerumenolytically acceptable enzyme is methyl trypsin, and said methyl trypsin is present in the amount of about 50 AU/ml to about 500 AU/ml.

34 (Original). The composition of claim 14 further comprising an enzyme stabilizing agent.

35 (Original). The composition of claim 34 wherein said enzyme stabilizing agent is selected from the group consisting of monomeric polyols, polymeric polyols, calcium ions, and borate/boric acid compound.

36 (Original). The composition of claim 35 wherein said enzyme stabilizing agent is glycerin.

37 (Canceled).

38 (Currently amended). The composition of claim ~~37~~14 wherein said bicarbonate is sodium bicarbonate.

39 (Original). The composition of claim 38 wherein said sodium bicarbonate is present in the amount about 0.5 weight/volume percent to about 15 weight/volume percent.

40 (Original). The composition of claim 39 wherein said cerumenolytically acceptable enzyme is methyl trypsin, and said methyl trypsin is present in the amount of about 50 AU/ml to about 500 AU/ml.

41 (Currently amended). A two-part composition, comprising:

a first part comprising a cerumenolytically acceptable enzyme in an amount effective to assist in the removal of human cerumen from the external ear canal; and

a second part comprising an aqueous otologically acceptable vehicle, said vehicle including a bicarbonate in an amount effective to assist in the removal of human cerumen from the external ear canal;

wherein said first and second parts are maintained separate until it is desired to administer said composition to said external ear canal, and wherein said first and second parts are mixed before said administration.

42 (Canceled).

43 (Currently amended). The composition of claim ~~42~~41 wherein said cerumenolytically acceptable enzyme is selected from the group consisting of lipases, proteases, amylases, and combinations or mixtures thereof.

44 (Original). The composition of claim 43 wherein said cerumenolytically acceptable enzyme is a proteolytic enzyme.

45 (Original). The composition of claim 44 wherein said proteolytic enzyme is selected from the group consisting of pancreatin, trypsin, subtilisin, collagenase,

keratinase, carboxypeptidase, papain, bromelain, aminopeptidase, elastase, Aspergillo peptidase, pronase E (from *S. griseus*), dispase (from *Bacillus polymyxa*), and combinations or mixtures thereof.

46 (Original). The composition of claim 44 wherein said proteolytic enzyme comprises a microbially derived enzyme.

47 (Original). The composition of claim 44 wherein said proteolytic enzyme comprises an alkyl trypsin.

48 (Original). The composition of claim 47 wherein said alkyl trypsin is methyl trypsin.

49 (Original). The composition of claim 48 wherein said bicarbonate is sodium bicarbonate.

50 (Original). The composition of claim 49 wherein said vehicle further comprises a demulcent.

51 (Original). The composition of claim 49 wherein said vehicle further comprises a surfactant.

52 (Original). The composition of claim 49 wherein said vehicle further comprises a preservative.

53 (Original). The composition of claim 49 wherein said vehicle further comprises a buffer.

54 (Original). The composition of claim 41 wherein said first part comprises an enzyme stabilizing agent.

55 (Original). The composition of claim 54 wherein said enzyme stabilizing agent is selected from the group consisting of monomeric polyols, polymeric polyols, calcium ions, and borate/boric acid compound.

56 (Original). The composition of claim 41 wherein said first part and said second part are packaged in separate bottles.

57 (Original). The composition of claim 41 wherein said first part and said second part are packaged in a device having a first container receiving said first part, a second container receiving said second part, and a non-permeable membrane separating said first container from said second container, and wherein said non-permeable membrane may be torn to allow mixing of said first part and said second part.

Claims 58-72 (Withdrawn).